

### ***Remarks/Arguments***

#### ***Remarks***

##### ***Amendments to the Claims***

After entry of the amendments presented herein, claims 27, 36, 92-95, 103, 111 and 122-125 will be pending in the captioned application. Claims 27, 36, 103, 111 and 122 are also amended herein without prejudice or disclaimer. After entry of the amendments presented herein, claims 27 and 123 are the independent claims. Applicants reserve the right to pursue the subject matter of the unamended claims in continuing applications. Further, the amendment of claims herein is done to further Applicants' business interests and prosecution of the captioned application.

The amendments to claim 27 are supported in the application as filed at page 29, lines 29-31 (mammalian); and page 24, line 11 (insulin) and page 22, lines 3-4 (recombinant).

The amendments to claim 36 removes the phrases, "agglomerated eukaryotic cell culture" and "eukaryotic cell culture", as these phrases are found in the claim from which it depends.

The amendment to claim 103 removes the phrase, "agglomerated eukaryotic cell culture", as this phrase is found in the claim from which it depends

The amendments to claim 111 are supported in the application as filed at page 34, lines 29-31; removes the phrase, "agglomerated eukaryotic cell culture", as this phrase is found in the claim from which it depends; and replaces the word, "eukaryotic", with the word, "mammalian", so that the claim has a correct antecedent basis.

The amendment to claim 122 removes the phrase, "agglomerated eukaryotic cell culture", as this phrase is found in the claim from which it depends.

Support for new claims 123-125 may be found, *inter alia*, in the specification at page 18, lines 1-16. Applicants point out that claim 123 is directed to protein-free mammalian cell culture media. The specification refers to a number of protein-free mammalian cell basal media. In particular, the protein-free basal media Dulbecco's Modified Eagle's Medium (DMEM), RPMI-1640, MCDB 131, MCDB 153, MDEM, IMDM, MEM, M199, McCoy's 5A, Williams' Media E, and Leibovitz's L-15 Medium are referred to at page 18, lines 2-4 of the specification. Further, the specification also notes that these media may be agglomerated (see page 17, line 22-27, page 18,

lines 1-4, and page 6, lines 13-16.) In view of the above, one skilled in the art would clearly recognize that Applicants were in possession of agglomerated protein-free mammalian cell culture medium powder as of the priority date of the captioned claims.

The amendments to the claims presented herein introduce no new matter.

### ***Arguments***

#### ***I. Rejections of the Claims Under 35 U.S.C. § 103.***

##### **I**

Unamended claims 27, 36, 92-95, 103, 111 and 122 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Peebles (U.S. Patent No. 2,835,586) in view of Fassolitis *et al.* (*Applied and Environmental Microbiology*, Vol. 42, No. 2, pp. 200-203 (1981)), Irvine *et al.* (U.S. Patent No. 4,692,338) and Wolfe *et al.* (U.S. Patent No. 5,232,848). (Office Action, page 3.) Applicants respectfully traverse the rejection, with respect these claims, as amended herein.

It is Applicants understanding that the Examiner is of the position that claims 27, 36, 92-95, 103, 111 and 122 are unpatentable under 35 U.S.C. § 103(a) on the basis that one skilled in the art would combine Peebles, Fassolitis *et al.*, Irvine *et al.* and Wolfe *et al.* to arrive at the claimed subject matter. In particular, the Examiner asserts that Peebles relates to a method of obtaining a dried milk powder, Fassolitis *et al.* relates to a method for the cultivation and/or growth of eukaryotic cells using a powdered nonfat dry skim milk filtrate (NDMF) as an eukaryotic cell culture medium, Irvine *et al.* relates to the manipulation of the pH of water-reconstituted spray-dried milk products by the addition of biological buffers during the spray-drying process, and Wolfe *et al.* relates to the beneficial use of biological buffers in the making of eukaryotic cell culture medium powders for the proliferation or cultivation of eukaryotic cell lines *in vitro*. (Office Action, pages 4-5.) As explained below, Applicants are of the position that one skilled in the art would not combine the cited art to arrive at the subject matter of the claims presented herein.

Applicants note that M.P.E.P. (8<sup>th</sup> Edition Revision 6, September 2007) § 2141.02, in pertinent part, states:

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious,

but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) . . .

In addition, when “an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.” (*See* M.P.E.P. § 2143.03.)

In order to simplify arguments presented herein, Applicants mainly address the issues initially with a focus on independent claim 27, as amended herein, and new independent claim 123. Claim 27, as amended herein, (underlining added) reads as follows:

27. An agglomerated mammalian cell culture medium powder prepared by agglomerating a dry powder mammalian cell culture medium with a solvent; wherein said agglomerated powder comprises a biological buffer and recombinant insulin and, upon being reconstituted with water, comprises all the necessary nutritive factors for the proliferation or cultivation of a mammalian cell *in vitro*.

Further, new independent claim 123 is directed to agglomerated *protein-free* mammalian cell culture medium powders prepared by agglomeration.

Applicants make the following points below in favor of patentability:

- (1) None of Peebles, Fassolitis *et al.*, Irvine *et al.* and Wolfe *et al.*, taken either alone or in combination, describe an agglomerated mammalian cell culture medium powder comprising recombinant insulin which falls within the scope of amended claim 27. Also, none of the cited references, taken either alone or in combination, describe an agglomerated mammalian cell culture medium powder which is protein-free and falls within the scope of new claim 123.
- (2) Four documents have been combined as the basis of the rejection of claims 27, 36, 92-95, 103, 111 and 122 under 35 U.S.C. § 103(a) prior to the amendments presented herein.

Each of these points is elaborated upon below.

With respect to Point 1, Applicants note that none of Peebles, Fassolitis *et al.*, Irvine *et al.* and Wolfe *et al.* discuss an agglomerated mammalian cell culture medium comprising recombinant insulin, as recited in amended claim 27. Likewise, none of the cited references discuss an agglomerated mammalian cell culture medium powder which is protein-free, as recited in new claim 123. Accordingly, Applicants respectfully submit that the cited references, taken either alone or in

combination, do not teach all the components recited by claim 27, as amended herein, or new claim 123. As such, Applicants also respectfully submit that the combination of the cited documents cannot be used to present a *prima facie* case of obviousness under 35 U.S.C. § 103(a) with respect to the claims presented herein.

With respect to Point 2, Applicants note that four documents have been combined to arrive at the rejection of unamended claim 27 and the claims which depend therefrom. Further, as discussed above, at least one component of the claimed agglomerated mammalian cell culture medium powder which fall within the scope of claim 27, as presented herein, is not discussed in any of these documents. Along these lines, the U.S. Supreme Court recently stated that:

[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although *common sense* directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and *claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.*

*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (U.S. 2007) (emphases added).

Thus, while clearly more than two documents may be combined to form the basis of a rejection under 35 U.S.C. § 103(a), the U.S. Supreme Court appears to have indicated that a common sense approach should be employed for determining whether claims are obvious. In view of this, it seems that the requirement that numerous documents be combined to arrive at the claimed invention as a whole points in favor of patentability over these documents.

In view of the above, Applicants respectfully submit that the claimed invention *as a whole* would not have been obvious at the time the invention was made to a person with ordinary skill in the art. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 103(a).

Unamended claims 27, 36, 92-95, 103, 111 and 122 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Getler *et al.* (International Publication No. WO 95/00031) in view of Fassolitis *et al.*, Irvine *et al.* and Wolfe *et al.* (Office Action, page 7.) Applicants respectfully traverse the rejection, with respect these claims, as amended herein.

Applicants note that the Examiner appears to assert that Getler *et al.* relates to milk and milk-like products, much like Pebbles. (Office Action, page 7.)

Similar to the arguments presented above, none of Getler *et al.*, Fassolitis *et al.*, Irvine *et al.* and Wolfe *et al.* disclose all of the components recited by the claims presented herein. Applicants note that none of the cited references discuss an agglomerated mammalian cell culture medium comprising recombinant insulin, as recited in amended claim 27. Likewise, none of the cited references discuss an agglomerated mammalian cell culture medium powder which is protein-free, as recited in new claim 123. Accordingly, Applicants respectfully submit that the cited references, taken either alone or in combination, do not teach all the components recited by claim 27, as amended herein, or new claim 123. As such, Applicants also respectfully submit that the subject matter of these claims would not be *prima facie* obvious under 35 U.S.C. § 103(a).

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 103(a).

### ***Conclusion***

Applicants respectfully request that this paper be entered. Applicants believe that a full and complete Reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned.

Prompt and favorable consideration and entry of this Amendment and Reply is respectfully requested.

Respectfully submitted,  
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